## (19) World Intellectual Property Organization

International Bureau





### (43) International Publication Date 10 March 2005 (10.03.2005)

#### **PCT**

# (10) International Publication Number WO 2005/020963 A1

- (51) International Patent Classification<sup>7</sup>: A61K 9/14, 9/20
- (21) International Application Number:

PCT/US2004/028345

(22) International Filing Date:

1 September 2004 (01.09.2004)

(25) Filing Language:

English

(26) Publication Language:

English

(30) Priority Data:

60/499,582

2 September 2003 (02.09.2003) US

- (71) Applicant (for BB only): IVAX CORPORATION [US/US]; 4400 Biscayne Boulevard, Miami, Florida 33137 (US).
- (71) Applicant (for all designated States except US): NORTON HEALTH CARE LTD. [GB/GB]; Albert Basin, Royal Docks, London E162QJ, United Kingdom (GB).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): XIAN-MING, Zeng [GB/GB]; 45 Hill Road, Mitcham, Surrey, CR4 2HS, United Kingdom (GB). SEAN, Kee Tee [GB/GB]; Flat 1, Cypress Lodge, 72 Brent View Road, The Hyde, London NW9 7EF, United Kingdom (GB).

- (74) Agent: Steinberg, Michael, A.; Ivax Corporation, 4400 Biscayne Boulevard, Miami, FL 33137 (US).
- (81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.



(57) Abstract: The present invention provides a process for preparing a particulate medicament that has greater homogeneity and a lower adhesion between the particles of the active ingredient and the carrier. The process comprises the steps of: (a) combining a pharmaceutically active ingredient in the form of an agglomerate of primary particles having an agglomerate particle size such that the agglomerate is capable of passing through a sieve having a mesh of 50-3000  $\mu$ m with a pharmaceutically acceptable particulate carrier, and (b) mixing the resultant material in a mixer to break up the agglomerate into primary particles dispersed in the pharmaceutically acceptable particulate carrier such that 90% or more of the pharmaceutically active ingredient exists as primary particles having a particle size of 50  $\mu$ m or less.

